

IN THE CLAIMS

Please cancel Claims 1-6 and add the following claims.

--> An immunoassay for detecting an antigen in a sample, comprising:

(a) sequentially contacting the sample with

(i) a first antibody which is capable of specifically binding to a first binding site on the antigen, wherein the first antibody is immobilized on an insoluble carrier, and then

(ii) a second antibody which is capable of specifically binding to a second binding site on the antigen, wherein the second antibody is free,

thereby forming, when the antigen is present in the sample, an agglutinate comprising the first antibody, the antigen, and the second antibody; followed by

(b) optically measuring the amount of the agglutinate.

8. The immunoassay of Claim 7, wherein said optically measuring comprises spectrophotometrically measuring decreasing light transmission due to formation of the agglutinate.

9. The immunoassay according to Claim 7, wherein the amount of the antigen in the sample is determined from a calibration curve.

10. The immunoassay of Claim 7, wherein the sample contains an undetectable amount of the antigen.

11. The immunoassay of Claim 7, wherein the sample contains a detectable quantity of the antigen.

12. The immunoassay of Claim 7, wherein the insoluble carrier is selected from the group consisting of organic polymeric substances, inorganic substances, cell membranes, hemocytes and microorganisms.

02

13. The immunoassay according to Claim 7, wherein the insoluble carrier is a latex particle.

14. The immunoassay of Claim 7, wherein the insoluble carrier is silica or alumina.

15. The immunoassay of Claim 7, wherein the insoluble carrier has an average particle size of 0.05 to 1 μm .

16. The immunoassay of Claim 7, wherein the sample is a buffered aqueous solution.

17. The immunoassay of Claim 7, wherein the antigen is selected from the group consisting of insulin, HCG- β , growth hormone, TSH, LH, FSH, prolactin, thyroxin, triiodothyronine, gastrin, glucagon, somatostatin, enzymes, serum proteins, clotting-fibrinolytic factors, HbA₁C, tumor-associated antigens, DNA-binding protein factors, cytokines, bacteria, viruses, and protozoa.

18. The immunoassay of Claim 7, wherein the sample does not contain an immune reaction-accelerating component.

19. The immunoassay of Claim 18, wherein the immune reaction-accelerating component is polyethylene glycol 6000.

20. The immunoassay of Claim 18, wherein the first antibody is a monoclonal antibody and the second antibody is a polyclonal antibody.

21. An immunoassay for detecting an antigen in a sample, comprising:
sub B~>
(a) sequentially contacting the sample with
(i) a first antibody which is capable of specifically binding to a first binding site on the antigen, wherein the first antibody is free, and then

(ii) a second antibody which is capable of specifically binding to a second binding site on the antigen, wherein the second antibody is immobilized on an insoluble carrier,

thereby forming, when the antigen is present in the sample, an agglutinate comprising the first antibody, the antigen, and the second antibody; followed by

(b) optically measuring the amount of the agglutinate.

22. The immunoassay of Claim 21, wherein said optically measuring comprises spectrophotometrically measuring decreasing light transmission due to formation of the agglutinate.

23. The immunoassay according to Claim 21, wherein the amount of the antigen in the sample is determined from a calibration curve.

24. The immunoassay of Claim 21, wherein the sample contains an undetectable amount of the antigen.

25. The immunoassay of Claim 21, wherein the sample contains a detectable quantity of the antigen.

26. The immunoassay of Claim 21, wherein the insoluble carrier is selected from the group consisting of organic polymeric substances, inorganic substances, cell membranes, hemocytes and microorganisms.

27. The immunoassay according to Claim 21, wherein the insoluble carrier is a latex particle.

28. The immunoassay of Claim 21, wherein the insoluble carrier is silica or alumina.

29. The immunoassay of Claim 21, wherein the insoluble carrier has an average particle size of 0.05 to 1 μm .

30. The immunoassay of Claim 21, wherein the sample is a buffered aqueous solution.

31. The immunoassay of Claim 21, wherein the antigen is selected from the group consisting of insulin, HCG- β , growth hormone, TSH, LH, FSH, prolactin, thyroxin, triiodothyronine, gastrin, glucagon, somatostatin, enzymes, serum proteins, clotting-fibrinolytic factors, HbA₁C, tumor-associated antigens, DNA-binding protein factors, cytokines, bacteria, viruses, and protozoa.

32. The immunoassay of Claim 21, wherein the sample does not contain an immune reaction-accelerating component.

33. The immunoassay of Claim 32, wherein the immune reaction-accelerating component is polyethylene glycol 6000.

34. The immunoassay of Claim 21, wherein the first antibody is a monoclonal antibody and the second antibody is a polyclonal antibody.--

SUPPORT FOR THE AMENDMENTS

Claims 7-34 are supported by the specification at pages 4-17 and by Claims 1-4. No new matter is believed to have been added to this application by these amendments.

REMARKS

Claims 7-34 are active in the present application.

Applicants would like to thank Examiner Spiegel for her helpful comments regarding claim amendments. The claims have been amended as suggested by the Examiner. Favorable reconsideration is respectfully requested.